



BAYLOR MEDICAL CENTER AT GRAPEVINE
A Subsidiary Community Hospital of the Baylor Health Care System

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Mark Hood, F.A.C.H.E.
Executive Director

FAX (817) 481-2962

August 3, 1999

Documents Branch
Food and Drug Administration
5630 Fishers Lane
Suite 1061
Rockville, MD 20852

Dear Sir:

I am writing you in regards to a draft guidance document (HFA-305) that proposes health providers initiate a HCV Lookback Program using a 1990 HCV test. The draft document also proposes providers "search historical records dating back indefinitely to the extent that electronics or other readily retrievable records exist."

I have followed the most recent requirement of a HCV Lookback (1992 test). This Lookback required going back to a date of January, 1988, not an indefinite period of time. This particular Lookback produced negligible results and caused undue concern and fright among senior citizens. The following results of this Lookback, as it pertains to one medical center, are indicative:

1. 528 units of blood were identified for final disposition.
2. 67% of those recipients identified had expired for non-related medical conditions.
3. A large number (123) tested positive before and after their blood transfusion. Therefore, the transfusion was not the cause of the positive test results.
4. The process finally focused on 20 recipients who were HCV positive. A great majority were senior citizens. Their responses, being informed, were negative. They included:
 - "Does this mean I won't be able to move to the nursing home?"
 - "I am retiring from work; does this mean it will take all my retirement money to cure me?"

Many of these senior citizens do not understand being informed about a medical condition that is not curable. They are not happy nor grateful. They are scared.

I understand the draft document (1990 test) shows a high percentage of false positive results. Another reason the proposed Lookback should not be initiated.

Please allow me to emphasize again, the 1992 Lookback produced negligible results. Senior citizens have all the medical worries they can handle. They do not comprehend being told they cannot be cured. When they convey their fears, I can assure you that moment in their lives can only be described as cruel.

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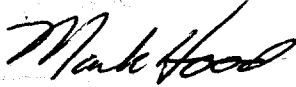
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I believe you will agree that all Lookback proposals need to be evaluated weighing the benefits to the patient. This is one that doesn't seem to pass the test. I do not believe the 1990 Lookback is justified.

To end this communication on a positive note, may I suggest the FDA consider patients who visit a hospital or physician's office, revealing a blood transfusion in their past, be tested for Hepatitis C. Why not consider a HCV test when a consumer goes to their physician for an annual physical? With the increase in the number of tattoo establishments, can we investigate some accountability regarding Hepatitis risks?

There has to be a better and more sensitive way to address this issue. Thank you for your consideration in this matter.

Sincerely,



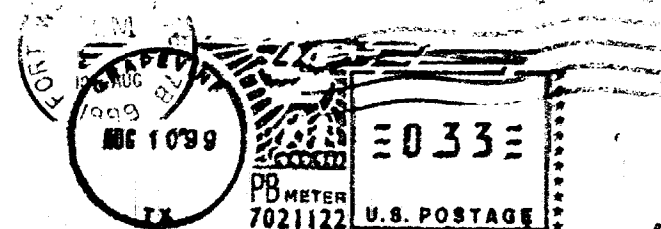
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pw

cc: Robin Biswas, M.D.
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